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(54) Title: MICROCOIL VASO-OCCLUSIVE DEVICE WITH MULTI-AXIS SECONDARY CONFIGURATION

(57) Abstract: A vaso-occlusive device includes a microcoil formed into a minimum energy state secondary configuration comprising a plurality of curved segments, each defining a discrete axis, whereby the device, in its minimum energy state configuration, defines multiple axes. In a preferred embodiment, the secondary configuration comprises a plurality of interconnected closed loops defining a plurality of discrete axes. In a second embodiment, the secondary configuration defines a wave-form like structure comprising an array of laterally-alternating open loops defining a plurality of separate axes. In a third embodiment, the secondary configuration forms a series of tangential closed loops, wherein the entire structure subtends a first angle of arc, and wherein each adjacent pair of loops defines a second angle of arc. In a fourth embodiment, the secondary configuration forms a logarithmic spiral. In all embodiments, the device, in its secondary configuration, has a dimension that is substantially larger than the largest dimension of the vascular site (i.e., aneurysm) in which it is to be deployed. Thus, confinement of the device within an aneurysm causes it to assume a three-dimensional configuration with a higher energy state than the minimum energy state. Because the minimum energy state configuration of the device is larger (in at least one dimension) than the aneurysm, the deployed device is constrained by its contact with the walls of the aneurysm from returning to its minimum energy state configuration. The engagement of the device with the aneurysm wall minimizes shifting or tumbling due to blood flow. Furthermore, the secondary configuration is not conducive to "coin stacking," thereby minimizing the compaction experienced.

MICROCOIL VASO-OCCCLUSIVE DEVICE WITH MULTI-AXIS SECONDARY CONFIGURATION

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a Continuation-in-Part of co-pending Application Serial No. 09/671,021; filed September 26, 2000.

FEDERALLY-SPONSORED RESEARCH OR DEVELOPMENT

Not Applicable

BACKGROUND OF THE INVENTION

This invention relates generally to the field of vascular occlusion devices and methods. More specifically, it relates to an apparatus and method for occluding a blood vessel by embolizing a targeted site (such as an aneurysm) in the blood vessel.

The embolization of blood vessels is desired in a number of clinical situations. For example, vascular embolization has been used to control vascular bleeding, to occlude the blood supply to tumors, and to occlude vascular aneurysms, particularly intracranial aneurysms. In recent years, vascular embolization for the treatment of aneurysms has received much attention. Several different treatment modalities have been employed in the prior art. U.S. Patent No. 4,819,637 - Dormandy, Jr. et al., for example, describes a vascular embolization system that employs a detachable balloon delivered to the aneurysm site by an intravascular catheter. The balloon is carried into the aneurysm at the tip of the catheter, and it is inflated inside the aneurysm with a solidifying fluid (typically a polymerizable resin or gel) to occlude the aneurysm. The balloon is then detached from the catheter by gentle traction on the catheter. While the balloon-type embolization device

1 can provide an effective occlusion of many types of aneurysms, it is difficult
2 to retrieve or move after the solidifying fluid sets, and it is difficult to visualize
3 unless it is filled with a contrast material. Furthermore, there are risks of
4 balloon rupture during inflation and of premature detachment of the balloon
5 from the catheter.

6 Another approach is the direct injection of a liquid polymer embolic
7 agent into the vascular site to be occluded. One type of liquid polymer used
8 in the direct injection technique is a rapidly polymerizing liquid, such as a
9 cyanoacrylate resin, particularly isobutyl cyanoacrylate, that is delivered to
10 the target site as a liquid, and then is polymerized *in situ*. Alternatively, a
11 liquid polymer that is precipitated at the target site from a carrier solution has
12 been used. An example of this type of embolic agent is a cellulose acetate
13 polymer mixed with bismuth trioxide and dissolved in dimethyl sulfoxide
14 (DMSO). Another type is ethylene glycol copolymer dissolved in DMSO.
15 On contact with blood, the DMSO diffuses out, and the polymer precipitates
16 out and rapidly hardens into an embolic mass that conforms to the shape of
17 the aneurysm. Other examples of materials used in this "direct injection"
18 method are disclosed in the following U.S. Patents: 4,551,132 - Pásztor et al.;
19 4,795,741 - Leshchiner et al.; 5,525,334 - Ito et al.; and 5,580,568 - Greff et al.

20 The direct injection of liquid polymer embolic agents has proven
21 difficult in practice. For example, migration of the polymeric material from
22 the aneurysm and into the adjacent blood vessel has presented a problem. In
23 addition, visualization of the embolization material requires that a contrasting
24 agent be mixed with it, and selecting embolization materials and contrasting
25 agents that are mutually compatible may result in performance compromises
26 that are less than optimal. Furthermore, precise control of the deployment of
27 the polymeric embolization material is difficult, leading to the risk of
28 improper placement and/or premature solidification of the material.

1 Moreover, once the embolization material is deployed and solidified, it is
2 difficult to move or retrieve.

3 Another approach that has shown promise is the use of thrombogenic
4 microcoils. These microcoils may be made of a biocompatible metal alloy
5 (typically platinum and tungsten) or a suitable polymer. If made of metal, the
6 coil may be provided with Dacron fibers to increase thrombogenicity. The
7 coil is deployed through a microcatheter to the vascular site. Examples of
8 microcoils are disclosed in the following U.S. patents: 4,994,069 - Ritchart et
9 al.; 5,122,136 - Guglielmi et al.; 5,133,731 - Butler et al.; 5,226,911 - Chee et
10 al.; 5,304,194 - Chee et al.; 5,312,415 - Palermo; 5,382,259 - Phelps et al.;
11 5,382,260 - Dormandy, Jr. et al.; 5,476,472 - Dormandy, Jr. et al.; 5,578,074 -
12 Mirigian; 5,582,619 - Ken; 5,624,461 - Mariant; 5,639,277 - Mariant et al.;
13 5,658,308 - Snyder; 5,690,667 - Gia; 5,690,671 - McGurk et al.; 5,700,258 -
14 Mirigian et al.; 5,718,711 - Berenstein et al.; 5,891,058 - Taki et al.; 6,013,084
15 - Ken et al.; 6,015,424 - Rosenbluth et al.; and Des. 427,680 - Mariant et al.

16 While many prior art microcoil devices have met with some success in
17 treating small aneurysms with relatively narrow necks, it has been recognized
18 that the most commonly used microcoil vaso-occlusive devices achieve less
19 than satisfactory results in wide-necked aneurysms, particularly in the
20 cerebrum. This has led to the development of three-dimensional microcoil
21 devices, such as those disclosed in U.S. Pat. Nos. 5,645,558 - Horton;
22 5,911,731 - Pham et al.; and 5,957,948 - Mariant (the latter two being in a
23 class of devices known as "three-dimensional Guglielmi detachable coils", or
24 "3D-GDC's"). See, e.g., Tan et al., "The Feasibility of Three-Dimensional
25 Guglielmi Detachable Coil for Embolisation of Wide Neck Cerebral
26 Aneurysms," *Interventional Neuroradiology*, Vol. 6, pp. 53-57 (June, 2000);
27 Cloft et al., "Use of Three-Dimensional Guglielmi Detachable Coils in the
28 Treatment of Wide-necked Cerebral Aneurysms," *American Journal of*

1 *Neuroradiology*, Vol. 21, pp. 1312-1314 (August, 2000).

2 The typical three-dimensional microcoil is formed from a length of
3 wire that is formed first into a primary configuration of a helical coil, and
4 then into a secondary configuration that is one of a variety of three-
5 dimensional shapes. The minimum energy state of this type of microcoil is its
6 three-dimensional secondary configuration. When deployed inside an
7 aneurysm, these devices assume a three-dimensional configuration, typically
8 a somewhat spherical configuration, that is at or slightly greater than, the
9 minimum energy state of the secondary configuration. Because the overall
10 dimensions of these devices in their non-minimum energy state configuration
11 is approximately equal to or smaller than the interior dimensions of the
12 aneurysm, there is nothing to constrain the device from shifting or tumbling
13 within the aneurysm due to blood flow dynamics.

14 In some of these three-dimensional devices (e.g., U.S. Pat. 5,122,136 -
15 Guglielmi et al.), the secondary configuration is itself a helix or some similar
16 form that defines a longitudinal axis. Devices with what may be termed a
17 “longitudinal” secondary configuration form a three-dimensional non-
18 minimum energy state configuration when deployed inside an aneurysm, but,
19 once deployed, they have displayed a tendency to revert to their minimum
20 energy state configurations. This, in turn, results in compaction due to “coin
21 stacking” (i.e., returning to the secondary helical configuration), thereby
22 allowing recanalization of the aneurysm.

23 There has thus been a long-felt, but as yet unsatisfied need for a
24 microcoil vaso-occlusive device that has the advantages of many of the prior
25 art microcoil devices, but that can be used effectively to treat aneurysms of
26 many different sizes configurations, and in particular those with large neck
27 widths. It would be advantageous for such a device to be compatible for use
28 with existing guidewire and microcatheter microcoil delivery mechanisms,

1 and to be capable of being manufactured at costs comparable with those of
2 prior art microcoil devices.

3

4 SUMMARY OF THE INVENTION

5 Broadly, the present invention is a filamentous vaso-occlusive device
6 that has a minimum energy state secondary configuration comprising a
7 plurality of curved segments, whereby the device, in its minimum energy state
8 configuration, defines multiple axes and/or foci. More specifically, each
9 segment defines either a plane and an axis that is substantially perpendicular
10 to the plane, or a path around the surface of a sphere, wherein the path is
11 defined by a unique locus located at the approximate center point of the
12 sphere around which the path is generated, and by a radius extending from
13 that locus that is equal to the radius of that sphere.

14 In a particular preferred embodiment, the present invention is an
15 elongate microcoil structure having a minimum energy state secondary
16 configuration that defines a plurality or series of tangentially-interconnected
17 closed loops, preferably substantially circular or elliptical, defining a plurality
18 of separate axes. In one form of the preferred embodiment, the closed loops
19 are substantially coplanar and define axes that are substantially parallel. That
20 is, the planes defined by the segments are themselves substantially coplanar.
21 In another form of the preferred embodiment, each pair of adjacent loops
22 defines a shallow angle, whereby their respective axes define an angle of not
23 more than about 90°, and preferably not more than about 45°, between them.
24 A further form of the preferred embodiment has the tangential loops arranged
25 so that the axis defined by each loop is orthogonal to a unique radius of a
26 circle, the radii being separated by a fixed angle of arc. In still another form
27 of the preferred embodiment, the loops, instead of being tangential, overlap.
28 In any of these forms, the loops may be of substantially uniform diameter, or

1 they may be of different diameters. For example, the first and/or last loop in
2 the series may be of a smaller diameter than the other loops, or the loops may
3 be in a series of loops of progressively decreased diameter, optionally with an
4 additional small-diameter loop preceding the largest diameter loop.

5 In first alternative embodiment, the microcoil structure has a minimum
6 energy state secondary configuration that defines a wave-form like structure
7 comprising a longitudinal array of laterally-alternating open loops defining a
8 plurality of separate axes. In a specific construction of this embodiment, the
9 wave-form like structure defines a substantially sinusoidal waveform wherein
10 each of the maxima and minima of the waveform defines an arc of radius r ,
11 and wherein each arc is connected to an adjacent arc by a straight section of
12 length L , wherein L is less than about $2r$. As in the preferred embodiment,
13 the alternative embodiment may be in a first form in which the loops are
14 substantially coplanar and their respective axes are substantially parallel, or in
15 a second form in which each pair of adjacent loops defines a shallow angle,
16 whereby their respective axes define an angle of not more than about 90° , and
17 preferably not more than about 45° , between them.

18 In a second alternative embodiment, the microcoil structure, in its
19 secondary configuration, forms a series of tangential closed loops, preferably
20 either substantially circular or elliptical, wherein the entire structure subtends
21 a first angle of arc, and wherein each adjacent pair of loops defines a second
22 angle of arc between them. Preferably, the first angle is greater than about
23 30° , and the second angle is less than about half of the first angle. It will be
24 seen that each loop defines an axis, with the angle formed by the axes of
25 adjacent loops being the second angle.

26 In a third alternative embodiment, the secondary configuration of the
27 microcoil structure forms preferably at least two interconnected equiangular
28 or logarithmic spirals, each defining a single unique axis. As used in this

1 specification, a logarithmic or equiangular spiral is defined as a curve that
2 cuts all radii vectors at a constant angle. Specifically, if the curve is a spiral,
3 that is, a curve in which the radial vector R is a monotonic increasing
4 function of the radial angle θ , the spiral will be an equiangular spiral if the
5 angle α formed between a radial vector R and the tangent for any point P on
6 the spiral is constant. In equiangular spirals having an angle α of greater than
7 about 70° , the configuration begins to resemble that of the shell of the
8 chambered nautilus. In the limiting case, it may be seen that a circle is an
9 equiangular spiral in which the angle α is 90° (the radial vector being a
10 radius).

11 In a fourth alternative embodiment, the secondary configuration of the
12 microcoil structure resembles a series of interconnected complex curved
13 segments, each of which is defined by a path around the surface of a sphere.
14 Each of the segments is thus defined by a unique focus located at the
15 approximate center point of the sphere around which the path is generated,
16 and by a radius extending from that locus that is equal to the radius of that
17 sphere. Each segment may be defined by radii that are coplanar (in the case
18 of a segment that is defined by a substantially circumferential path around its
19 defining sphere), or by radii that lie in different planes intersecting the sphere
20 (where path around the defining sphere deviates from a circumferential path).
21 The segments thus resemble nearly, but not fully, completed circles
22 (circumferential path) or helical loops (non-circumferential path), and they
23 may be either of uniform or different diameters.

24 In any of the embodiments, the device is preferably formed from a
25 microcoil structure, but it may alternately be formed of a flexible,
26 filamentous, non-coil structure. Known non-coil structures used in vaso-
27 occlusive devices include, but are not limited to, wires, slotted wires, spiral
28 cut wires, tubes, slotted tubes, spiral cut tubes, polymer filaments,

1 polymer/metal composite filaments, and micro-chains.

2 In any of the embodiments, the device, in its minimum energy state
3 secondary configuration, has a dimension that is substantially larger
4 (preferably at least about 25% greater) than the largest dimension of the
5 vascular space in which the device is to be deployed. Most preferably, the
6 length of the device, in its minimum energy state secondary configuration,
7 should be at least about twice the maximum diameter of the targeted
8 aneurysm or other vascular site in which the device is to be installed. Also, it
9 is advantageous to provide in the device at least one curved segment having a
10 diameter, in the minimum energy state secondary configuration, that is
11 approximately equal to the largest diameter of the targeted aneurysm or
12 vascular site. Thus, when the device is deployed inside a vascular site such as
13 an aneurysm, the confinement of the device within the site causes the device
14 to assume a three-dimensional configuration that has a higher energy state
15 than the minimum energy state. Because the minimum energy state of the
16 device is larger (in at least one dimension) than the space in which it is
17 deployed, the deployed device is constrained by its intimate contact with the
18 walls of the aneurysm from returning to its minimum energy state
19 configuration. Therefore, the device still engages the surrounding aneurysm
20 wall surface, thereby minimizing shifting or tumbling due to blood flow
21 dynamics. Furthermore, the minimum energy state secondary configuration
22 (to which the device attempts to revert) is not one that is conducive to "coin
23 stacking", thereby minimizing the degree of compaction that is experienced.

24 As will be better appreciated from the detailed description that follows,
25 the present invention provides for effective embolization of vascular structures
26 (particularly aneurysms) having a wide variety of shapes and sizes. It is
27 especially advantageous for use in wide-necked aneurysms. Furthermore, as
28 will be described in more detail below, the present invention may be deployed

using conventional deployment mechanisms, such as microcatheters and guidewires.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a microcoil vaso-occlusive device in accordance with a preferred embodiment of the present invention;

Figure 2 is a partial view of the device of Figure 1, taken within the area designated by the numeral 2 in Figure 1;

Figures 3 and 4 are partial views of a microcoil vaso-occlusive device in accordance with another form of the preferred embodiment of the present invention;

Figure 5 is a plan view of a microcoil vaso-occlusive device in accordance with a first alternative embodiment of the invention;

Figure 6 is an elevational view of the present invention in the process of being deployed through a microcatheter into a wide-necked aneurysm;

Figure 7 is a perspective view of a heat treatment fixture used to manufacture the preferred embodiment of the present invention;

Figure 8 is a perspective view of a second alternative embodiment of the invention;

Figure 9 is an elevational view of the second alternative embodiment of Figure 8;

Figure 10 is a plan view of another form of the first alternative embodiment of the invention:

Figure 11 is a plan view of a third alternative embodiment of the invention:

Figures 12-15 are plan views of other forms of the preferred embodiment of the invention:

Figure 16 is a perspective view of a fourth alternative embodiment of

1 the invention, showing how it is formed on a specialized heat treatment
2 fixture, the latter being shown in a simplified, idealized form; and

3 Figure 17 is an elevational view of still another form of the preferred
4 embodiment of the present invention.

5

6 DETAILED DESCRIPTION OF THE INVENTION

7 Referring first to Figures 1-4 and 8, a microcoil vaso-occlusive device
8 10, in accordance with a preferred embodiment of the invention is shown.
9 The device 10 comprises a suitable length of wire formed into the primary
10 configuration of a helical microcoil 12 (Figure 2). Suitable materials for the
11 device 10 include platinum, rhodium, palladium, rhenium, tungsten, gold,
12 silver, tantalum, and various alloys of these metals. Various surgical grade
13 stainless steels may also be used. Preferred materials include the
14 platinum/tungsten alloy known as Platinum 479 (92% Pt, 8% W, available
15 from Sigmund Cohn, of Mount Vernon, NY) and titanium/nickel alloys
16 (such as the titanium/nickel alloy known as "nitinol"). Another material that
17 may be advantageous is a bimetallic wire comprising a highly elastic metal
18 with a highly radiopaque metal. Such a bimetallic wire would also be
19 resistant to permanent deformation. An example of such a bimetallic wire is
20 a product comprising a nitinol outer layer and an inner core of pure reference
21 grade platinum, available from Sigmund Cohn, of Mount Vernon, NY; and
22 Anomet Products, of Shrewsbury, MA. Wire diameters of about 0.0125 mm
23 to about 0.150 mm may be used.

24 The microcoil 12 has a diameter that is typically in the range of about
25 0.125 mm to about 0.625 mm, with a preferred a preferred range, for most
26 neurovascular applications, of about 0.25 mm to about 0.40 mm. The axial
27 length of the microcoil 12 may be anywhere from about 5 mm to about 1000
28 mm, with about 20 mm to about 400 mm being typical.

1 The primary winding of the microcoil 12 is applied under tension. The
2 amount of tension, and the pitch of the primary winding, determine the
3 stiffness of the microcoil 12. These parameters can be varied along the length
4 of the microcoil 12 to form a microcoil having different degrees of stiffness
5 along its length, which may be advantageous in certain applications.

6 The microcoil 12 is formed into a secondary configuration that
7 comprises a plurality of curved segments, each defining an axis, whereby the
8 microcoil 12 defines multiple axes. More specifically, each of the curved
9 segments defines a plane an axis that is substantially perpendicular to the
10 plane. In the preferred embodiment of Figures 1-4, the curved segments are
11 tangentially-interconnected closed loops 14a, 14b that are substantially
12 circular, and that define a plurality of separate axes 16. In one form of the
13 preferred embodiment, shown in Figure 1, the loops 14a, 14b are substantially
14 coplanar and define axes 16 that are substantially parallel. In another form
15 of the preferred embodiment, shown in Figures 3 and 4, each pair of adjacent
16 loops 14a, 14b defines a shallow angle, whereby their respective axes 16
17 define an angle (θ_1 , θ_2 , θ_3 , and θ_4) of not more than about 90° between them,
18 and preferably not more than about 45°.

19 The preferred embodiment of the invention typically includes a pair of
20 end loops 14a and at least one intermediate loop 14b. Typically, there will be
21 up to four intermediate loops 14b, depending on the vascular site to be
22 embolized, but there may be as many as six or more, for use in very large
23 vascular sites. The intermediate loops are sized to have a diameter
24 approximately equal to the maximum diameter of the target vascular site
25 (e.g., an aneurysm), while the end loops 14a have a slightly smaller diameter
26 (preferably, approximately 1.5 mm smaller), for purposes to be described
27 below.

28 The primary microcoil 12 is formed into the secondary configuration

1 by heat treatment, as is well known in the art. For example, the annealed
2 primary coil may be initially placed into the secondary configuration by
3 winding or wrapping around a suitably shaped and sized mandrel of
4 refractory material, and then subjected to an annealing temperature for a
5 specified period of time. For Platinum 479, for example, an annealing
6 temperature of about 500°C to about 1000°C, preferably approximately
7 670°C, is maintained for about 30 to 90 minutes, preferably about 60
8 minutes, then cooled to room temperature and ultrasonically cleaned. The
9 resultant secondary configuration is thereby made permanent, and it becomes
10 the minimum energy state configuration of the microcoil 12.

11 Figure 7 shows a heat treatment fixture 50 used in the manufacture of
12 the preferred embodiment of the invention. The fixture 50 is made of a
13 refractory material, and it includes a base 52 having a surface on which is
14 provided a mandrel for the secondary winding. The mandrel comprises a
15 plurality of winding pins 54a, 54b extending upwardly from the surface of the
16 base 52. The exemplary fixture 50 shown in the drawing has six pins
17 arranged in roughly a hexagonal pattern. There are two end winding pins 54a
18 adjacent each other, and four intermediate winding pins 54b. A pair of
19 fastening pegs 56 is located near one end of the fixture, for fastening the ends
20 of the primary coil 12.

21 The diameters of the end winding pins 54a are slightly smaller than the
22 diameters of the intermediate winding pins 54b to achieve the size
23 relationships described above. The spacings between the pins 54a, 54b are
24 only slightly greater than the diameter of the primary coil 12, so that only one
25 wind of the primary coil can be passed around the pins with each winding of
26 the secondary coil. Each subsequent winding of the secondary coil is thus
27 stacked on top of the previous winding. This eliminates any straight sections
28 in the secondary coil, which, during deployment, would tend to push the coil

1 into the parent artery.

2 During the secondary winding process, the primary coil 12 is kept
3 under tension. The amount of tension can be adjusted to control the degree of
4 spring-back of the loops 14a, 14b of the microcoil 12.

5 The secondary winding of the microcoil 12 is performed so that the
6 loops 14a, 14b reverse direction as the microcoil 12 is wrapped around each
7 successive pin on the fixture. This ensures that loops will not coin stack, and
8 that they will disperse randomly throughout the aneurysm once deployed.
9 Furthermore, in the preferred embodiment, each loop is wound a complete
10 360° before the next loop is wound. This ensures that each loop will
11 completely seat within the aneurysm before the microcoil 12 reverses
12 direction. With a complete loop intact, the loop strength is maximized, and
13 the loop distributes loads evenly.

14 Figures 12-15 and 17 illustrate alternative forms of the above-described
15 preferred embodiment. Specifically, in Figure 12, a microcoil 12' has a
16 secondary configuration that includes a plurality of connected curved
17 segments, wherein the curved segments are overlapping connected closed
18 loops 14', that are substantially circular, with each loop 14' defining a separate
19 axis 16'. In Figure 13, a microcoil 12" has a secondary configuration that
20 includes a plurality of connected curved segments, wherein the curved
21 segments are tangentially-interconnected, substantially elliptical loops 14",
22 each defining a separate axis 16". Figures 14 and 15 show alternative forms
23 that are similar to that of Figures 1-4, except that the loops are of different
24 diameters. Thus, in Figure 14, a microcoil 12"" has a secondary configuration
25 that includes a plurality of tangentially-interconnected, substantially circular
26 loops 14"" of progressively decreasing diameter, starting from a loop 14""c of
27 the largest diameter, each of the loops defining a unique axis 16"". The
28 variant form shown in Figure 15 is similar to that of Figure 14, except that

1 there is an additional small-diameter loop 14^{iv}d preceding the largest
2 diameter loop 14^{iv}c. A further form of the preferred embodiment, illustrated
3 in Figure 17, comprises a microcoil 12^{iv} having a minimum energy state
4 secondary configuration in which a plurality of interconnected, tangential
5 loops 14^{iv} are arranged so that each loop defines an axis 16^{iv} that is orthogonal
6 to a unique radius r of a circle, the radii being separated by a fixed angle of
7 arc θ .

8 Figure 5 shows a microcoil vaso-occlusion device 20 in accordance
9 with a first alternative embodiment of the invention. This embodiment
10 includes a primary microcoil 22 formed into a secondary minimum energy
11 state configuration that defines a wave-form like structure comprising a
12 longitudinal array of laterally-alternating open loops 24 defining a plurality of
13 separate axes 26. As in the preferred embodiment, the alternative
14 embodiment may be in a first form in which the loops 24 are substantially
15 coplanar and their respective axes 26 are substantially parallel, or in a second
16 form in which each pair of adjacent loops 24 defines a shallow angle, whereby
17 their respective axes 26 define an angle of not more than about 90°, and
18 preferably not more than about 45°, between them. The materials,
19 dimensions, and method of manufacture of this alternative embodiment are,
20 in all material respects, similar to those of the preferred embodiment
described above.

22 Figure 10 illustrates a specific construction of this embodiment,
23 wherein the primary microcoil structure 22' is formed into a secondary
24 minimum energy state configuration having a wave-form like structure that
25 defines a substantially sinusoidal waveform, defining a plurality of separate
26 axes 26'. The waveform has at least one maximum 22a and at least one
27 minimum 22b, each of which defines an arc of radius r , and wherein each arc
28 is connected to an adjacent arc by a straight section of length L , wherein L is

1 less than about 2r.

2 The method of using the present invention is shown in Figure 6. In
3 use, the proximal end of the microcoil 12 (or 22) is attached to the distal end
4 of an elongate delivery device, such as a guidewire or microcatheter (not
5 shown). The attachment may be by any of a number of ways known in the
6 art, as exemplified by the following U.S. patents, the disclosures of which are
7 expressly incorporated herein by reference: 5,108,407 - Geremia et al.;
8 5,122,136 - Guglielmi et al.; 5,234,437 - Sepetka; 5,261,916 - Engelson;
9 5,304,195 - Twyford, Jr. et al.; 5,312,415 - Palermo; 5,423,829 -Pham et al.;
10 5,522,836 - Palermo; 5,645,564 - Northrup et al.; 5,725,546 - Samson;
11 5,800,453 - Gia; 5,814,062 - Sepetka et al.; 5,911,737 - Lee et al.; 5,989,242 -
12 Saadat et al.; 6,022,369 - Jacobsen et al. 6,063,100 - Diaz et al.; 6,068,644 -
13 Lulo et al.; and 6,102,933 - Lee et al.

14 A target vascular site is visualized, by conventional means, well-
15 known in the art. The target vascular site may be an aneurysm 40 branching
16 off a parent artery 42. The aneurysm 40 has a dome 44 connected to the
17 branch artery by a neck 46. A catheter 30 is passed intravascularly until it
18 enters the dome 44 of the aneurysm 40 via the neck 46. The microcoil 12 is
19 passed through the catheter 30 with the assistance of the guidewire or
20 microcatheter until the microcoil 12 enters the dome 44 of the aneurysm 40.

21 The undersized end loop 14a at the distal end of the microcoil 12 enters
22 the aneurysm first. This assists in seating the first loop properly, because the
23 smaller size keeps the first loop inside the neck 46 of the aneurysm, avoiding
24 the parent artery 42.

25 The intermediate loops 14b then enter the aneurysm. Because they are
26 sized to fit the aneurysm, they can deploy freely and smoothly with minimal
27 friction against the wall of the aneurysm. Because the secondary
28 configuration of the microcoil 12 is essentially coplanar, all of the

1 intermediate loops exert a force against the walls of the aneurysm dome 44,
2 thereby improving the resistance of the microcoil 12 to shifting due to
3 pulsatile blood flow.

4 As the microcoil 12 enters the aneurysm, it attempts to assume its
5 secondary configuration. Because the microcoil, in its secondary
6 configuration, is larger than the aneurysm, however, it is constrained into a
7 deployed configuration in which it tends to line the periphery of the
8 aneurysm. In this deployed configuration, the microcoil is in an energy state
9 that is substantially higher than its minimum energy state. Thus, when the
10 device is deployed inside a vascular site such as an aneurysm, the
11 confinement of the device within the site causes the device to assume a three-
12 dimensional configuration that has a higher energy state than the minimum
13 energy state. Because the minimum energy state of the device is larger (in at
14 least one dimension) than the space in which it is deployed, the deployed
15 device is constrained by its intimate contact with the walls of the aneurysm
16 from returning to its minimum energy state configuration. Therefore, the
17 device still engages the surrounding aneurysm wall surface, thereby
18 minimizing shifting or tumbling due to blood flow dynamics. Furthermore,
19 the minimum energy state secondary configuration (to which the device
20 attempts to revert) is not one that is conducive to "coin stacking", thereby
21 minimizing the degree of compaction that is experienced.

22 The undersized end loop 14a at the proximal end of the microcoil 12
23 enters the aneurysm last. After the microcoil is fully deployed, it is
24 controllably detached from the delivery device by any suitable means well-
25 known in the art, thereby allowing the delivery device to be withdrawn,
26 leaving the microcoil in place to embolize the aneurysm. After detachment,
27 the proximal end loop 14a curls into the neck 46 of the aneurysm 40, avoiding
28 the parent artery 42.

1 The microcoil is designed with a maximum loops diameter that is
2 dimensioned to line the periphery of the aneurysm upon deployment, as
3 mentioned above. For larger aneurysms, it is advantageous to fill in a
4 substantial portion of the interior volume of the aneurysm by deploying one
5 or more additional microcoils, of progressively smaller maximum loop
6 diameter.

7 Figures 8 and 9 illustrate a vaso-occlusion device in accordance with a
8 second alternative embodiment of the invention. This embodiment includes a
9 primary microcoil 60 formed into a secondary minimum energy state
10 configuration that forms a series of tangential closed loops 62 (preferably
11 substantially circular or elliptical), wherein the entire structure subtends a first
12 angle of arc θ_1 , and wherein each adjacent pair of circles or ellipses defines a
13 second angle of arc θ_2 between them. Preferably, the first angle θ_1 is greater
14 than about 30°, and the second angle θ_2 is less than about half of the first
15 angle θ_1 . Although not illustrated in the drawings, it will be appreciated that
16 each loop 62 defines an axis, whereby the angle formed between the axes of
17 adjacent loops 62 is equal to θ_2 .

18 Figure 11 illustrates a vaso-occlusive device in accordance with a third
19 alternative embodiment of the invention. In this embodiment, a microcoil 70
20 has a secondary configuration that forms at least a pair of connected
21 equiangular or logarithmic spirals 72, each of the spirals defining an axis 73
22 that is orthogonal to the plane defined by the spiral. For the purpose of this
23 specification, an equiangular or logarithmic spiral is defined as a curve that
24 cuts all radii vectors at a constant angle, where a radial vector R is defined as
25 a line drawn from any point P on the spiral to the center of the spiral.
26 Specifically, if the curve is a spiral, that is, a curve having a radial vector R
27 that is a monotonic increasing function of the radial angle θ , the spiral will be
28 an equiangular spiral if the angle α formed between a radial vector and the

1 tangent for any point P on the spiral is constant.

2 Figure 16 illustrates a vaso-occlusive device in accordance with a
3 fourth alternative embodiment, wherein a microcoil 80 has a secondary
4 configuration that resembles a series of interconnected complex curved
5 segments 82, each of which is defined by a path around the surface of a sphere
6 84. Each of the segments is thus defined by a unique focus 86 located at the
7 approximate center point of the sphere 84 around which the path is generated,
8 and by a radius r extending from that locus 86 that is equal to the radius of
9 that sphere. Each segment may be defined by radii that are coplanar (in the
10 case of a segment that is defined by a substantially circumferential path
11 around its defining sphere), or by radii that lie in different planes intersecting
12 the sphere (where path around the defining sphere deviates from a
13 circumferential path). The segments thus resemble nearly, but not fully,
14 completed circles (circumferential path) or helical loops (non-circumferential
15 path), and they may be either of uniform or different diameters.

16 The present invention thus exhibits several advantages over prior art
17 three-dimensional microcoils. For example, there is increased coverage of the
18 aneurysm neck, due to the presence of loops across the neck, yet the
19 probability of any part of the device intruding into the parent artery is
20 reduced. The secondary coil configuration also provides smoother
21 deployment, and, once deployed, the device exhibits greater resistance to coil
22 compaction, thereby increasing positional stability in the face of pulsatile
23 blood flow. This stability is achieved with lower overall friction between the
24 device and the aneurysm wall. Moreover, the random distribution of loops
25 throughout the aneurysm allows the device to maintain a complex shape
26 inside the aneurysm, yielding improved embolization.

27 While a preferred embodiment and alternative embodiments of the
28 invention have been described herein, it will be appreciated that a number of

1 variations and modifications will suggest themselves to those skilled in the
2 pertinent arts. For example, other secondary configurations than those
3 described herein may be found that will yield most, if not all, of the
4 significant advantages of the invention for treatment of the typical aneurysm,
5 or that will prove especially advantageous in specific clinical applications.
6 Also, for specific applications, the dimensions and materials may be varied
7 from those disclosed herein if found to be advantageous. These and other
8 variations and modifications are considered to be within the spirit and scope
9 of the invention, as defined in the claims that follow.

1 WHAT IS CLAIMED IS:

2 1. A vaso-occlusive device comprising a filamentous structure formed
3 into a minimum energy state secondary configuration comprising a plurality
4 of curved segments, each defining a discrete axis, whereby the device, in its
5 minimum energy state configuration, defines multiple axes.

6

7 2. The device of Claim 1, wherein each of the curved segments defines
8 a plane and an axis that is substantially perpendicular to the plane.

9

10 3. The device of Claim 1, wherein the multiple axes are substantially
11 parallel.

12

13 4. The device of Claim 1, wherein each adjacent pair of the multiple
14 axes forms an acute angle.

15

16 5. The device of Claim 1, wherein the curved segments are
17 substantially closed loops, interconnected to each other.

18

19 6. The device of Claim 1, wherein the curved segments are wave-like
20 open loops.

21

22 7. The device of Claim 6, wherein open loops define a substantially
23 sinusoidal waveform.

24

25 8. The device of Claim 7, wherein the waveform has a maximum and
26 a minimum, wherein each of the maximum and minimum defines an arc of
27 radius length r , and wherein each arc is connected to an adjacent arc by a
28 straight section having a length that is less than about $2r$.

1 9. The device of Claim 5, wherein the closed loops are arranged
2 tangentially to each other.

3

4 10. The device of Claim 5, wherein at least one of the loops overlaps
5 an adjacent loop.

6

7 11. The device of Claim 9, wherein each loop defines an axis that is
8 orthogonal to a unique radius of a circle, wherein the radii are separated by a
9 fixed angle of arc.

10

11 12. The device of Claim 5, wherein the device comprises a plurality of
12 loops of progressively decreasing diameter from a largest loop to a smallest
13 loop.

14

15 13. The device of Claim 12, wherein the smallest loop is a first smallest
16 loop, and wherein device further comprises a second smallest loop
17 immediately adjacent the largest loop.

18

19 14. The device of Claim 1, wherein the device is dimensioned for
20 installation in a vascular site having a predetermined maximum dimension,
21 and wherein the device has at least one dimension, in its secondary
22 configuration, that is at least 25% greater than the maximum dimension of the
23 vascular site.

24

25 15. The device of Claim 1, wherein the device is dimensioned for
26 installation in a vascular site having a predetermined maximum diameter, and
27 wherein the device, in its secondary configuration, has at least one curved
28 segment having a diameter that is approximately equal to the maximum

1 wherein the device, in its secondary configuration, has at least one curved
2 segment having a diameter that is approximately equal to the maximum
3 diameter of the vascular site.

4

5 30. The device of Claim 28, wherein the device has a length, in its
6 secondary configuration, that is at least twice the maximum dimension of the
7 vascular site.

8

9 31. The device of Claim 20, wherein the filamentous element is
10 selected from the group consisting of a microcoil, a wire, a slotted wire, a
11 spiral cut wire, a tube, a slotted tube, a spiral cut tube, a polymer filament, a
12 polymer/metal composite filament, and a micro-chain.

13

14 32. A method of embolizing a vascular site having a predetermined
15 maximum diameter, comprising the steps of:

16 (a) providing vaso-occlusive device comprising a filamentous structure
17 formed into a minimum energy state secondary configuration comprising a
18 plurality of interconnected curved segments, whereby the device, in its
19 minimum energy state configuration, has a length that is at least about 25%
20 larger than the maximum diameter of the vascular site; and

21 (b) deploying the device into the interior of the vascular site so that
22 device is contained within the vascular site in a configuration having an
23 energy state that is substantially higher than its minimum energy state,
24 whereby the device is constrained by its contact with the vascular site from
25 returning to its minimum energy state configuration.

26

27 33. The method of Claim 32, wherein the device has a length in its
28 minimum energy state secondary configuration that is at least about twice the

1 maximum diameter of the vascular site.

2

3 34. The method of Claim 32, wherein the device, in its minimum
4 energy state secondary configuration, has at least one curved segment having
5 a diameter that is approximately equal to the maximum diameter of the
6 vascular site.

7

8 35. The method of Claim 32, wherein each of the curved segments is a
9 substantially closed loop, each defining a discrete axis.

10

11 36. The method of Claim 32, wherein each of the curved segments is a
12 wave-like open loop, each defining a discrete axis.

13

14 37. The method of Claim 32, wherein each of the curved segments is a
15 logarithmic spiral.

16

17 38. The method of Claim 32, wherein each of the curved segments is
18 defined by a path around the surface of a sphere, the path being defined by a
19 unique locus at the approximate center point of the sphere around which the
20 path is generated, and by a radius extending from the center point that is
21 equal to the radius of the sphere.

22

23 39. A vaso-occlusive device for embolizing a vascular site having a
24 predetermined maximum diameter, the device comprising:

25 a filamentous structure formed into a minimum energy state secondary
26 configuration comprising a plurality of curved segments, whereby the device,
27 in its minimum energy state configuration, has a length that is at least about
28 25% larger than the maximum diameter of the vascular site.

1 40. The device of Claim 39, wherein the device has a length in its
2 minimum energy state secondary configuration that is at least about twice the
3 maximum diameter of the vascular site.

4

5 41. The device of Claim 39, wherein the device, in its minimum
6 energy state secondary configuration, has at least one curved segment having
7 a diameter that is approximately equal to the maximum diameter of the
8 vascular site.

9

10 42. The device of Claim 39, wherein each of the curved segments is a
11 substantially closed loop, each defining a discrete axis.

12

13 43. The device of Claim 39, wherein each of the curved segments is a
14 wave-like open loop, each defining a discrete axis.

15

16 44. The device of Claim 39, wherein each of the curved segments is a
17 logarithmic spiral.

18

19 45. The device of Claim 39, wherein each of the curved segments is
20 defined by a path around the surface of a sphere, the path being defined by a
21 unique locus at the approximate center point of the sphere around which the
22 path is generated, and by a radius extending from the center point that is
23 equal to the radius of the sphere.

FIG. 1

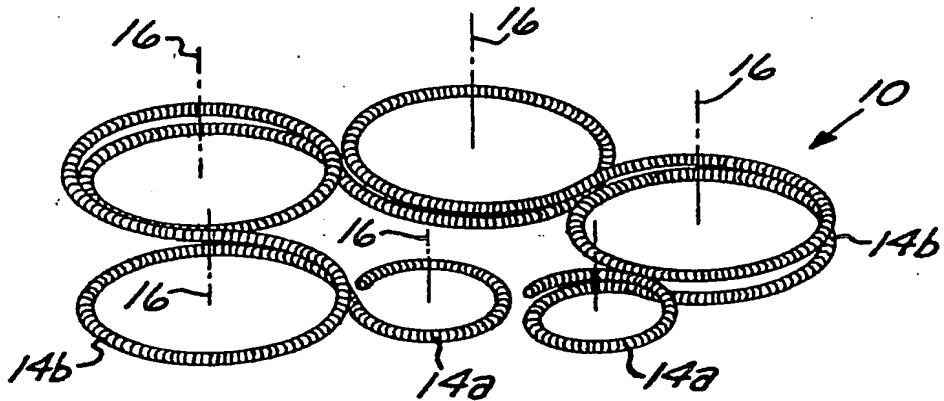


FIG. 2

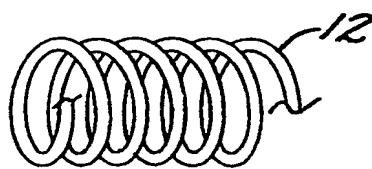


FIG. 3

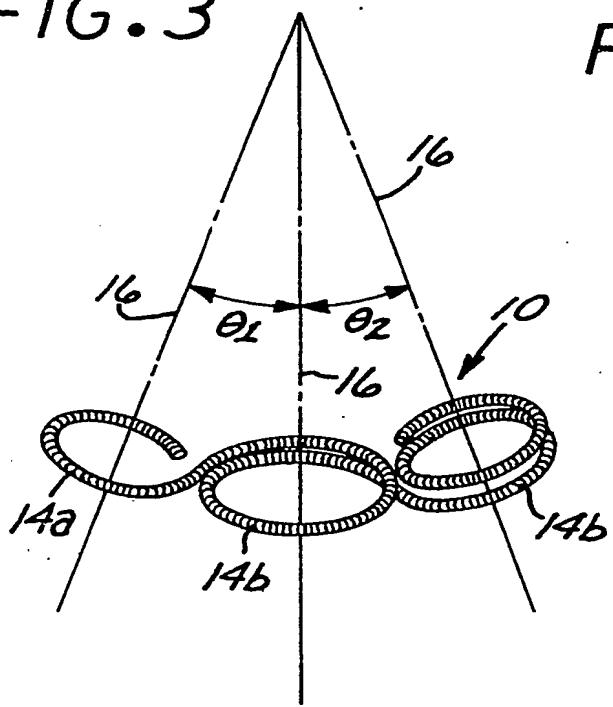
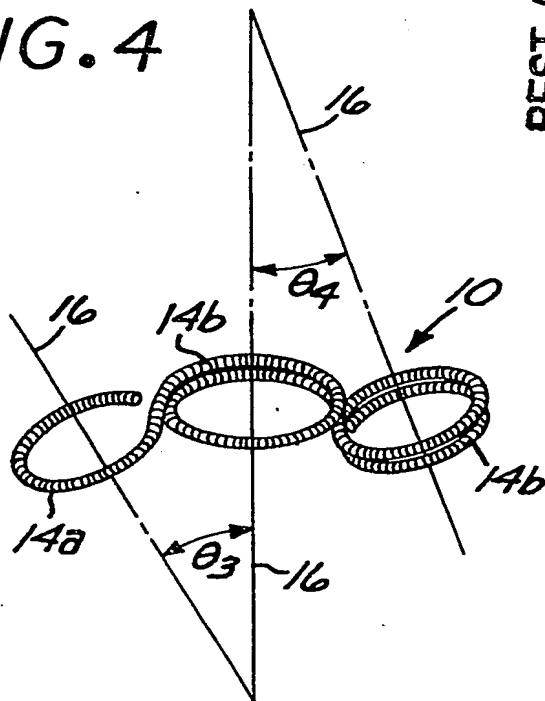


FIG. 4



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FIG. 5

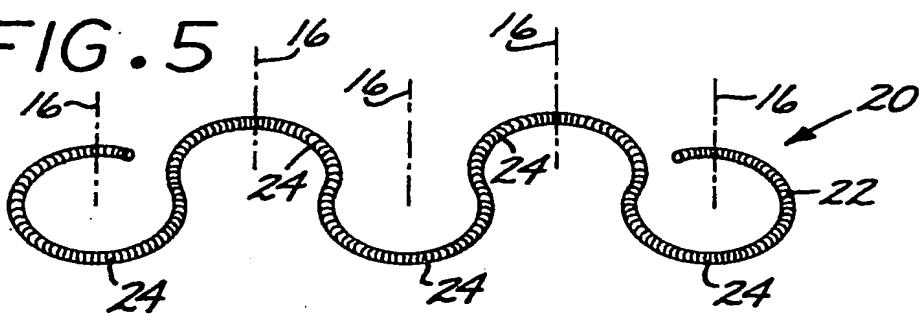
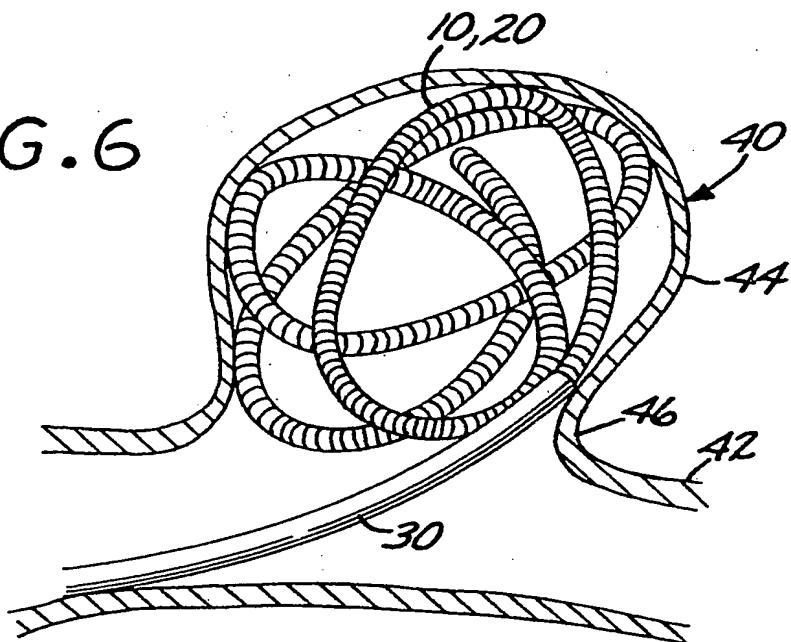


FIG. 6



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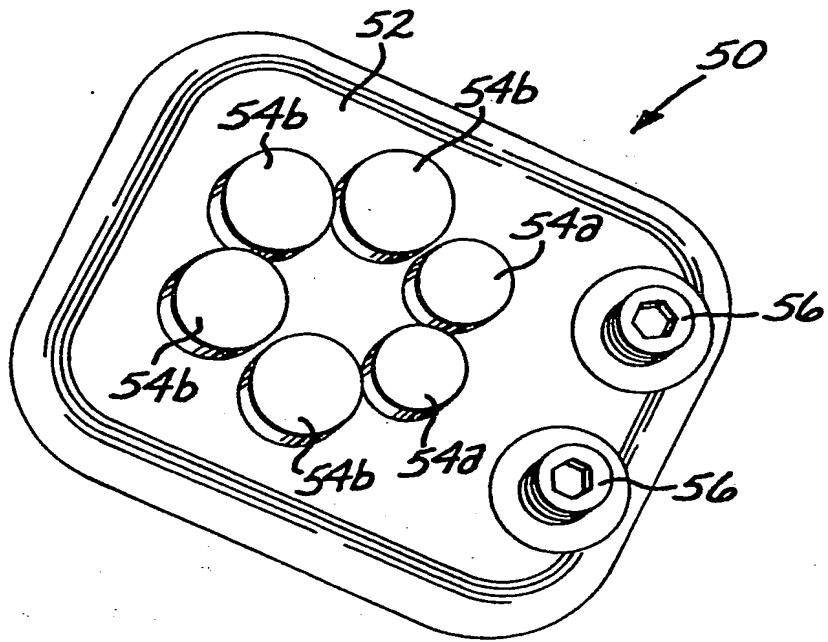


FIG. 7

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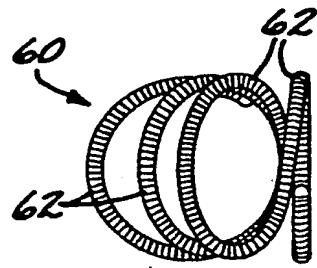


FIG. 8

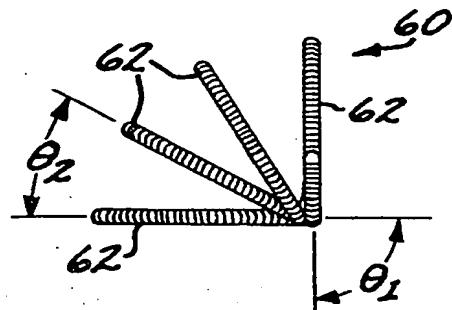


FIG. 9

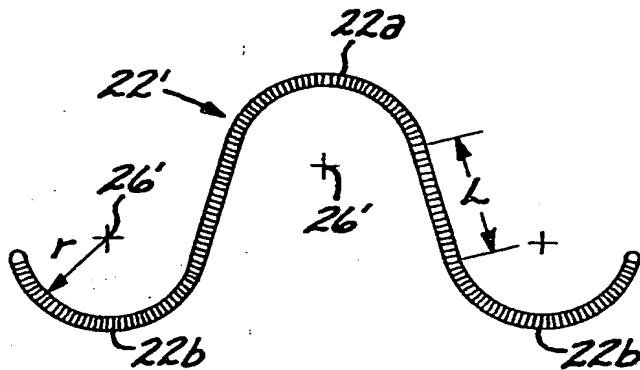


FIG. 10

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FIG. 11

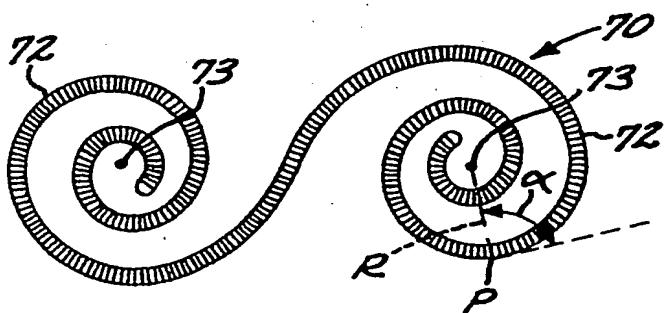


FIG.12

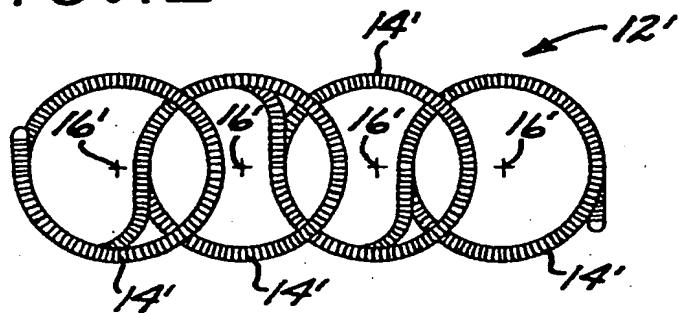


FIG.13

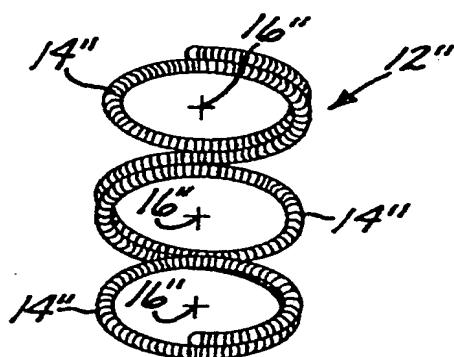
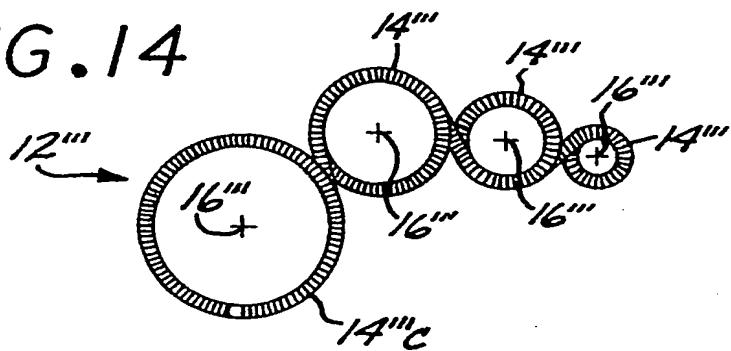


FIG.14



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FIG. 15

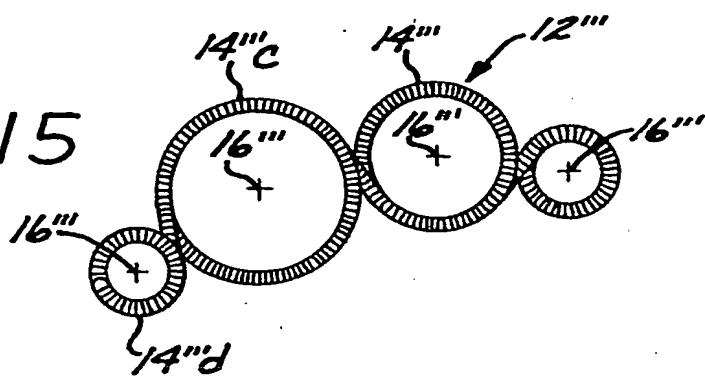
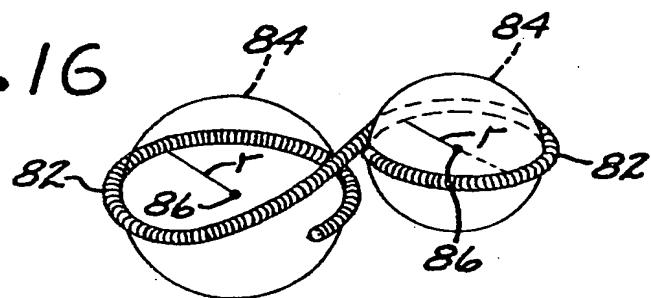
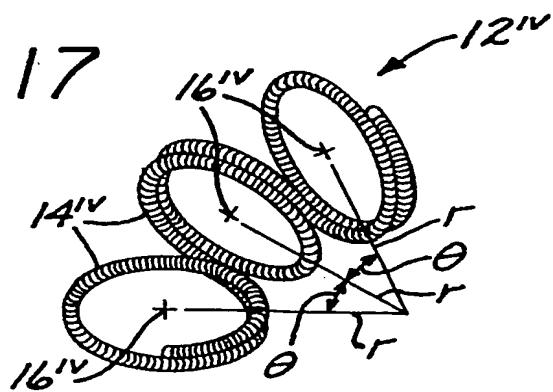


FIG. 16



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FIG. 17



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(19) World Intellectual Property Organization International Bureau



(43) International Publication Date
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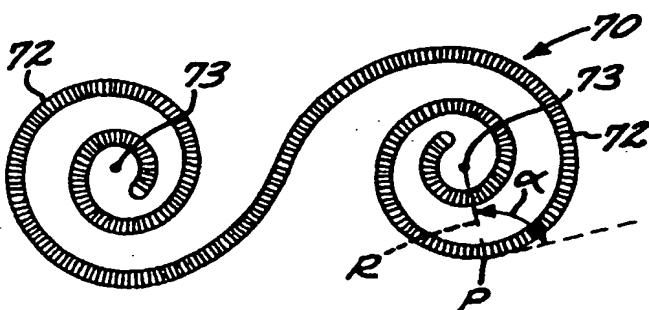
PCT

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10/043,947 11 January 2002 (11.01.2002) US
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- (74) Agent: Howard, J., Klein; Klein, O'neill & Singh, LLP, Suite 510, 2 Park Plaza, Irvine, CA 92614 (US).
- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW.
- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
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8 April 2004

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: MICROCOIL VASO-OCCLUSIVE DEVICE WITH MULTI-AXIS SECONDARY CONFIGURATION



WO 2003/059176 A3

series of tangential closed loops, wherein the entire structure subtends a first angle of arc, and wherein each adjacent pair of loops defines a second angle of arc. In a fourth embodiment, the secondary configuration forms a logarithmic spiral. In all embodiments, the device, in its secondary configuration, has a dimension that is substantially larger than the largest dimension of the vascular site (i.e., aneurysm) in which it is to be deployed. Thus, confinement of the device within an aneurysm causes it to assume a three-dimensional configuration with a higher energy state than the minimum energy state. Because the minimum energy state configuration of the device is larger (in at least one dimension) than the aneurysm, the deployed device is constrained by its contact with the walls of the aneurysm from returning to its minimum energy state configuration. The engagement of the device with the aneurysm wall minimizes shifting or tumbling due to blood flow. Furthermore, the secondary configuration is not conducive to "coin stacking," thereby minimizing the compaction experienced.

(57) Abstract: A vaso-occlusive device includes a microcoil formed into a minimum energy state secondary configuration comprising a plurality of curved segments, each defining a discrete axis, whereby the device, in its minimum energy state configuration, defines multiple axes. In a preferred embodiment, the secondary configuration comprises a plurality of interconnected closed loops defining a plurality of discrete axes. In a second embodiment, the secondary configuration defines a wave-form like structure comprising an array of laterally-alternating open loops defining a plurality of separate axes. In a third embodiment, the secondary configuration forms a

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 03/00779

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 280 457 B1 (WALLACE MICHAEL P ET AL) 28 August 2001 (2001-08-28) column 9, line 62 -column 10, line 14; figures 2A,2B ---	1-5,9
X	WO 01 93780 A (MICRUS CORP) 13 December 2001 (2001-12-13)	1,6-8
A	page 11, line 17 - line 31; figure 9 ---	12
X	US 5 536 274 A (NEUSS MALTE) 16 July 1996 (1996-07-16) column 7, line 36 - line 58; figure 7B ---	1,5,10
X	WO 00 21443 A (COOK INC) 20 April 2000 (2000-04-20) page 13, line 10 - line 30; figure 18 page 15, line 28 - line 30 ---	1,5,11
	-/-	

 Further documents are listed in the continuation of box C. Patent family members are listed in annex.

° Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
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Date of the actual completion of the international search

Date of mailing of the international search report

30 June 2003

Name and mailing address of the ISA
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Authorized officer

Angelis, M

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 03/00779

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 02100 A (ANSON MEDICAL LTD ; QURESHI SHAKEEL (GB); REIDY JOHN (GB); ANSON AN) 22 January 1998 (1998-01-22) page 14, paragraph 1; figure 11 -----	1,5,12

INTERNATIONAL SEARCH REPORT

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: -32-38 because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. Claims Nos.: 15-31 because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
Pages 22 and 23 of the application, including claims 20-28 and part of claims 15 and 29, have not been filed and therefore the latter claims could not be searched. Further, claims 30 and 31 could not be searched, as they relate to claims 28 and 20.
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-13

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 03/00779

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